

## CLAIMS

WHAT IS CLAIMED IS:

- 1                   1.       An apparatus for collection and lateral flow chromatography of an  
2 oral fluid, said apparatus comprising:  
3                   a capillary matrix having exposed a surface for receiving oral fluid;  
4 and  
5                   a lateral flow chromatography strip where said lateral flow  
6 chromatography strip is in communication with said capillary matrix such that when said  
7 capillary matrix receives oral fluid, said capillary matrix wicks up said oral fluid and delivers  
8 said oral fluid to a receiving area of said lateral flow chromatography strip.
- 1                   2.       The apparatus of claim 1, wherein saturation of said capillary matrix  
2 with an oral fluid does not substantially alter the morphology of said capillary matrix.
- 1                   3.       The apparatus of claim 2, wherein saturation of said capillary matrix  
2 with an oral fluid does not substantially alter the average pore size of said capillary matrix.
- 1                   4.       The apparatus of claim 2, wherein saturation of said capillary matrix  
2 with an oral fluid does not substantially alter the void volume of said capillary matrix.
- 1                   5.       The apparatus of claim 2, wherein said capillary matrix has an average  
2 pore size ranging from about 40  $\mu\text{m}$  to about 250  $\mu\text{m}$ .
- 1                   6.       The apparatus of claim 2, wherein said capillary matrix has a void  
2 volume of less than about 60%/cm<sup>3</sup>.
- 1                   7.       The apparatus of claim 1, wherein said capillary matrix comprises a  
2 plastic.
- 1                   8.       The apparatus of claim 7, wherein said capillary matrix comprises a  
2 plastic selected from the group consisting of a high density polyethylene (HDPE), an ultra-  
3 high molecular weight polyethylene (UHMW), a polypropylene (PP), a polyvinylidene

4 fluoride (PVDF), a polytetrafluoroethylene (PTFE), a nylon 6 (N6), and a polyethersulfone  
5 (PES).

1 9. The apparatus of claim 7, wherein said plastic is hydrophilic or treated  
2 to be hydrophilic.

1 10. The apparatus of claim 1, wherein said capillary matrix, when  
2 contacted to an oral mucosa takes up oral fluid from said oral cavity and releases said oral  
3 fluid to said receiving area of said lateral flow chromatography strip in under about 1  
4 minute.

1 11. The apparatus of claim 10, wherein said capillary matrix, when  
2 contacted to an oral mucosa takes up oral fluid from said oral cavity and releases said oral  
3 fluid to said receiving area of said lateral flow chromatography strip in under about 30  
4 seconds.

1 12. The apparatus of claim 10, wherein said capillary matrix, is saturated  
2 with oral fluid in under about 1 minute.

1 13. The apparatus of claim 1, wherein said capillary matrix is saturated by  
2 less than about 500  $\mu$ L.

1 14. The apparatus of claim 1, wherein said capillary matrix releases said  
2 oral fluid to said receiving area of said lateral flow chromatography strip without  
3 compression of said capillary matrix.

1 15. The apparatus of claim 14, wherein sufficient oral fluid is released to  
2 saturate said receiving area.

1 16. The apparatus of claim 1, further comprising a blocking strip placed  
2 between the capillary matrix and the lateral flow chromatographic strip said blocking strip  
3 comprising a detergent.

1 17. The apparatus of claim 16, wherein said blocking strip further  
2 comprises a buffer.

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1           18.    The apparatus of claim 16, wherein said blocking strip prevents  
2 backflow of reagents from said lateral flow chromatography strip to said capillary matrix.

3           19.    The apparatus of claim 1, further comprising:  
4                   a housing having a cavity, wherein said lateral flow chromatography  
5 strip extends into the cavity along the housing to an inspection site on the housing; and  
6                   at least one inspection site from an exterior of the housing to the  
7 lateral chromatographic strip to enable visual inspection of reagents at selected sites on the  
8 lateral chromatographic strip.

1           20.    The apparatus of claim 19, wherein said housing acts as a handle for  
2 inserting said capillary matrix into said oral cavity.

1           21.    A method of detection or quantifying one or more analytes in an oral  
2 fluid, said method comprising the steps of:

3                   i) inserting into the oral cavity of a mammal an apparatus comprising  
4 a capillary matrix attached to a lateral flow chromatography strip, such that said capillary  
5 matrix is contacted with an oral mucosal surface whereby said capillary matrix wicks up oral  
6 fluid and delivers said oral fluid to a receiving area of said lateral flow chromatography strip;  
7 and

8                   ii) reading a signal on said lateral flow chromatography strip that  
9 indicates the presence absence or quantity of said one or more analytes.

1           22.    The method of claim 21, wherein saturation of said capillary matrix  
2 with an oral fluid does not substantially alter the morphology of said capillary matrix.

1           23.    The method of claim 22, wherein saturation of said capillary matrix  
2 with an oral fluid does not substantially alter the average pore size of said capillary matrix.

1           24.    The method of claim 22, wherein saturation of said capillary matrix  
2 with an oral fluid does not substantially alter the void volume of said capillary matrix.

1           25.    The method of claim 22, wherein said capillary matrix has an average  
2 pore size ranging from about 40  $\mu\text{m}$  to about 250  $\mu\text{m}$ .

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1                   26.    The method of claim 22, wherein said capillary matrix has a void  
2 volume of less than about 60%/cm<sup>3</sup>.

1                   27.    The method of claim 21, wherein said capillary matrix comprises a  
2 plastic.

1                   28.    The method of claim 27, wherein said capillary matrix comprises a  
2 plastic selected from the group consisting of a high density polyethylene (HDPE), an ultra-  
3 high molecular weight polyethylene (UHMW), a polypropylene (PP), a polyvinylidene  
4 fluoride (PVDF), a polytetrafluoroethylene (PTFE), a nylon 6 (N6), and a polyethersulfone  
5 (PES).

1                   29.    The method of claim 27, wherein said plastic is hydrophilic or treated  
2 to be hydrophilic.

1                   30.    The method of claim 21, wherein said capillary matrix, when  
2 contacted to an oral mucosa takes up oral fluid from said oral cavity and releases said oral  
3 fluid to said receiving area of said lateral flow chromatography strip in under about 1  
4 minute.

1                   31.    The method of claim 30, wherein said said capillary matrix, when  
2 contacted to an oral mucosa takes up oral fluid from said oral cavity and delivers about 100  
3 :L to about 200 :L of oral fluid to said lateral flow chromatography strip in under about 1  
4 minute.

1                   32.    The method of claim 30, wherein said capillary matrix, when  
2 contacted to an oral mucosa takes up oral fluid from said oral cavity and releases said oral  
3 fluid to said receiving area of said lateral flow chromatography strip in under about 30  
4 seconds.

1                   33.    The method of claim 30, wherein said capillary matrix, is saturated  
2 with oral fluid in under about 1 minute.

1                   34.    The method of claim 21, wherein said capillary matrix is saturated by  
2 less than about 500 µL.

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1           35.    The method of claim 21, wherein said capillary matrix releases said  
2 oral fluid to said receiving area of said lateral flow chromatography strip without  
3 compression of said capillary matrix.

1           36.    The method of claim 35, wherein sufficient oral fluid is released to  
2 saturate said receiving area.

1           37.    The method of claim 21, wherein said apparatus further comprises a  
2 blocking strip placed between the capillary matrix and the lateral flow chromatographic strip  
3 said blocking strip comprising a detergent.

1           38.    The method of claim 37, wherein said blocking strip further comprises  
2 a buffer.

1           39.    The method of claim 37, wherein said blocking strip prevents  
2 backflow of reagents from said lateral flow chromatography strip to said capillary matrix.

1           40.    The method of claim 21, wherein said apparatus further comprises:  
2                   a housing having a cavity, wherein said lateral flow chromatography  
3 strip extends into the cavity along the housing to an inspection site on the housing; and  
4                   at least one inspection site from an exterior of the housing to the  
5 lateral chromatographic strip to enable visual inspection of reagents at selected sites on the  
6 lateral chromatographic strip.  
7  
8

1           41.    The method of claim 40, wherein said housing acts as a handle for  
2 inserting said capillary matrix into said oral cavity.

1           42.    A kit for the detection of an analyte in an oral fluid, said kit  
2 comprising:  
3                   an apparatus for collection and lateral flow chromatography of an oral  
4 fluid of claim 1; and  
5                   instructional materials describing the use of said apparatus.  
6

1                   43.     An apparatus for oral lateral strip chromatography to detect test  
2 analytes in oral fluid within an oral cavity comprising:  
3                   a housing;  
4                   a cavity in the housing;  
5                   a lateral chromatography strip extending into the cavity from the  
6 cavity along the housing to an inspection site on the housing, the lateral chromatography  
7 strip having reagents for binding test analytes;  
8                   at least one inspection site from an exterior of the housing to the  
9 lateral chromatographic strip to enable visual inspection of reagents at selected sites on the  
10 lateral chromatographic strip;  
11                  a hydrophilic capillary matrix communicating from the housing to the  
12 oral cavity at one end and having communication to the lateral chromatographic strip at the  
13 other end.

1                   44.     Apparatus for oral lateral strip chromatography to detect test analytes  
2 in oral fluid within the oral cavity according to claim 43 and further comprising:  
3                   a blocking strip placed between the hydrophilic capillary matrix and  
4 the lateral chromatographic strip for blocking unwanted substances from the porous  
5 adsorptive wick.

1                   45.     Apparatus for oral lateral strip chromatography to detect test analytes  
2 in oral fluid within the oral cavity according to claim 43 and further comprising:  
3                   the hydrophilic capillary matrix defining a matrix of channels from  
4 material having spherical particles.

1                   46.     Apparatus for oral lateral strip chromatography to detect test analytes  
2 in oral fluid within the oral cavity according to claim 43 and further comprising:  
3                   the hydrophilic capillary matrix defining a matrix of channels from  
4 material selected from the group including plastic polymer and polystyrene.

1                   47.     Apparatus for oral lateral strip chromatography to detect test analytes  
2 in oral fluid within the oral cavity according to claim 43 wherein the hydrophilic capillary  
3 matrix does not increase its volume during transport of oral fluid.

1                   48.     A process of transporting test analytes in oral fluid from an oral cavity  
2 to a lateral chromatographic strip comprising the steps of:

3                             providing a lateral chromatographic strip;  
4                             providing a housing with a cavity in the housing;  
5                             providing a lateral chromatography strip extending into the cavity  
6 along the housing to an inspection site on the housing;  
7                             providing a hydrophilic capillary matrix communicating from the  
8 housing to the oral cavity at one end and having communication to the lateral  
9 chromatographic strip at the other end;  
10                            communicating the hydrophilic capillary matrix at the one end to the  
11 mouth of a person to be tested; and,  
12                            observing the lateral chromatographic strip for inspection of reagents  
13 at the selected sites on the lateral chromatographic strip.

1                   49.     A process of transporting aqueous fluid from the oral cavity to a  
2 lateral chromatographic strip according to claim 48 and comprising the further step of:  
3                             providing at least one control site from the exterior of the housing to  
4 the lateral chromatographic strip to indicate presence of a minima of fluid to be sampled  
5 received from the absorbent pad to the lateral chromatographic strip.

1                   50.     A process of transporting aqueous fluid from the oral cavity to a  
2 lateral chromatographic strip according to claim 48 and comprising the further step of:  
3                             hydrophilic capillary matrix defining a matrix of channels from  
4 material having spherical particles.

1                   51.     A process of transporting aqueous fluid from the oral cavity to a  
2 lateral chromatographic strip according to claim 48 and comprising the further step of:  
3                             hydrophilic capillary matrix defining a matrix of channels from  
4 material selected from the group including plastic polymer and polystyrene.

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- 1                    52.    A process of transporting aqueous fluid from the oral cavity to a  
2 lateral chromatographic strip according to claim 48 and comprising the further step of:  
3                    the provided hydrophilic capillary matrix does not increase its volume  
4 during transport of aqueous fluid.

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